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SpineSmith Cimplicity Spinal System

510(k) Summary of Safety and Effectiveness

SUBMITTED BY	SpineSmith Partners, LP 8140 N. Mopac, Bldg II, Suite 120 Austin, TX 78759
ESTABLISHMENT REGISTRATION NUMBER	3006404071
CONTACT PERSON	Robert Jones Vice President, Research and Development Phone: 512-206-0770 Fax: 512-637-6750 Email: rjones@spinesmithusa.com
SUBMISSION PREPARED BY	Lisa Peterson Kaedon Consulting, LLC Phone: 512-507-0746
DATE PREPARED	April 2, 2008
CLASSIFICATION	MQP 888.3060- Spinal Intervertebral Body Fixation Orthosis ODP 888.3080 - Intervertebral fusion device with bone graft, cervical
COMMON NAME	Spinal Vertebral Body Replacement System (MQP) Intervertebral body fusion device (ODP)
PROPRIETARY NAME	SpineSmith Cimplicity Spinal System
PREDICATE DEVICE(S)	SpineSmith Cimplicity Spinal System (K073320) LDR Spine MC+ (K043479) Spinal Elements, Inc. Crystal (K073351)
SUBSTANTIAL EQUIVALENCE	The SpineSmith Cimplicity System was determined to be substantially equivalent to several commercially available systems.

DEVICE DESCRIPTION

Cimplicity is a rectangular shaped implant, which is available in a parallel or lordotic configuration of various heights. Cimplicity is hollow to allow for the placement of allograft or autograft bone. There are teeth on the superior and inferior surface of the device to provide increased stability and inhibit movement of the implant.

INDICATIONS:

The Cimplicity System is indicated for use to replace a vertebral body that has been resected or excised (i.e. partial or total vertebrectomy) due to tumor or trauma/fracture. The Cimplicity device is intended for use in the thoracolumbar spine (from T1 to L5) and is intended for use with supplemental internal fixation. These devices are designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column even in the absence of fusion for a prolonged period. These devices are intended to be used with autograft or allograft bone.

When used as an intervertebral body fusion device, the Cimplicity System is indicated for anterior cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one level from the C2-C3 disc to the C7-TI disc. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. Cimplicity implants are to be used with autogenous bone graft and implanted via an open, anterior approach.

MECHANICAL TEST DATA

Mechanical test results demonstrate that the proposed Cimplicity System is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Spine Smith Partners
% Mr. Robert Jones
Vice President, Research and Development
8140 North Mopac
Building II, Suite 120
Austin, TX 78759

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Re: K080971
Trade/Device Name: Cimplicity Spinal System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal vertebral body fixation device
Regulatory Class: II
Product Code: MQP, ODP
Dated: April 2, 2008
Received: April 4, 2008

Dear Mr. Jones:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K080971

Device Name: SpineSmith Partners, LP **Cimplicity System**

Indications for Use:

The Cimplicity System is indicated for use to replace a vertebral body that has been resected or excised (i.e. partial or total vertebrectomy) due to tumor or trauma/fracture. The Cimplicity device is intended for use in the thoracolumbar spine (from T1 to L5) and is intended for use with supplemental internal fixation. These devices are designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column even in the absence of fusion for a prolonged period. These devices are intended to be used with autograft or allograft bone.

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K080971